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## Improving metabolic control in NIDDM patients referred for insulin therapy

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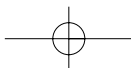
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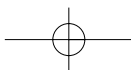
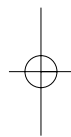
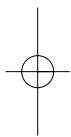
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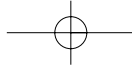
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## CHAPTER 5





**VALIDITY AND RELIABILITY OF THE DIABETES HEALTH PROFILE**  
*Measurement of Psychosocial Status in Referred NIDDM Patients*

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## ABSTRACT

Recently, a new specific diabetes questionnaire, the Diabetes Health Profile (DHP), has been developed to identify psychosocial dysfunctioning of insulin-requiring (NIDDM) and insulin-dependent diabetes mellitus (IDDM) patients. The DHP comprises three dimensions: psychological distress (PSY: 14 items), barriers to activity (BAR: 12 items), and disinhibited eating (EAT: 5 items). This study investigates the psychometric properties of the DHP in Dutch non-insulin-dependent diabetes mellitus (NIDDM) patients referred for insulin therapy. In addition, the relationship between patient characteristics and the DHP outcome was examined. The factor structure found was similar but not identical to former studies, but internal consistency was supported by high correlations of our factor structure and the original factor outcome and Cronbach's  $\alpha$ . The three factors explained 32% of the variance, subscribing earlier findings. It was shown that Cronbach's  $\alpha$  was satisfactory (0.72, 0.72, and 0.79). Strong and significant correlations between the PSY/BAR dimensions and predicted corresponding scales of the RAND-36 supported convergent validity. However, the PSY/BAR dimensions also showed, although less strong, significant correlations with the non-corresponding RAND-36 scales. The EAT dimension showed only correlations with two of the RAND-36 dimensions, thus measuring a different trait. Regression analysis showed that older patients had less problems with items of the EAT dimension and that no difference was found between men and women, supports earlier findings. The hyperglycaemic complaint 'fatigue' gave a significantly lower score (more problems) on the PSY and BAR dimensions. Younger age, the presence of hypertension and retinopathy gave a significant lower score on the EAT dimension. DHP outcome was not significantly influenced by duration of diabetes, GHb (indicator of glycemic control), serum total cholesterol, body mass index, chronic diabetes complications, and co-morbidity. Overall, the psychometric properties were good considering the small and different sample, suggesting that the DHP is promising for use in NIDDM patients, although more study is necessary in a larger sample.

## INTRODUCTION

Non-insulin-dependent diabetes mellitus (NIDDM) is a chronic disease and a major cause of mortality and morbidity.<sup>1</sup> Long-term complications include cardiovascular problems, renal failure, blindness, and amputations<sup>2</sup>, resulting in a lowered quality of life.

It is generally assumed that strict glycemc control will prevent or delay the development of chronic diabetic complications in NIDDM, which has already been demonstrated in insulin-dependent diabetes mellitus (IDDM) by the Diabetes Control and Complications Trial.<sup>3</sup> Above that, the view is that people with diabetes mellitus whose disease is well controlled through oral hypoglycaemic agents (OHA) and or (multiple) daily injections of insulin, continuous blood glucose self-monitoring, exercise, and a well-balanced diet will experience fewer symptoms than those less well controlled, and that this control regimen will improve their quality of life.<sup>4,5</sup>

Besides the biochemical control, it is important to evaluate the quality of life of the patient and the impact of diabetes on the patient's psychological and behavioral functioning in the provision and monitoring of the quality of care.<sup>6-9</sup> Quality of life can be assessed by generic- and disease specific questionnaires. Generic measures enable comparisons across different studies and disease groups. However, the lack of disease specific content can make them less sensitive in identifying disease related dysfunctioning and responsiveness to therapeutic effects.

The Diabetes Health Profile (DHP) is a recently developed disease specific questionnaire developed by Meadows et al.<sup>10</sup> for the identification of psychosocial functioning of insulin-dependent (IDDM) and insulin-requiring patients, NIDDM patients treated with insulin therapy. In contrast to the work of Meadows et al. , this study evaluates the reliability and validity of the DHP in a Dutch group of NIDDM patients, currently not on insulin but referred for insulin therapy in order to assess the appropriateness of the DHP for this group of patients. In addition to this evaluation, we examined the relationship between patients characteristics and the outcome of the DHP.

## RESEARCH DESIGN AND METHODS

### *Study population*

The Zwolle Study started in May 1993. Between May 1993 and September 1994 consecutive patients with NIDDM, referred by their general practitioners for insulin therapy to the outpatient department of Hospital 'the Weezenlanden', were included following informed consent.<sup>11</sup> Patients were referred by general practitioners in or around Zwolle. The study was approved by the local scientific and ethical committee.

### *Instruments*

The DHP (see appendix) was developed to identify psychological and behavioral dysfunctioning in insulin-dependent and insulin-requiring patients in an ambulatory care setting. Its reliability and validity were found to be satisfactory in earlier studies<sup>10</sup>. The DHP measures 3 dimensions: 'Psychological distress', 'Barriers to activity', and 'Disinhibited eating'. The 'Psychological distress' dimension (14 items) relates to diabetes-specific and non-specific content reflecting important components of psychological dysfunctioning, encompassing aspects of vulnerability to breakdown under stress and proneness to emotional instability, e.g. feelings of hopelessness, irritability, hostility, and dysphoric mood. The 'Barriers to activity' dimension (13 items) reflects activity-restricting anxiety relating to patients' perceptions of behavioral restrictions, social impairment due to diabetes, experiences of psychological disturbance, anxiety reducing behaviour such as increased management adherence, and avoidance behaviour (i.e. not going out too far alone, not going into busy or crowded places). One of the 13 items, a question concerning insulin injections (item 31), was omitted, because patients using insulin were excluded from this phase of the study. The 'Disinhibited eating' dimension (5 items) reflects the disinhibiting effects of emotional arousal on eating behaviour (e.g. eating extra when feeling bored or fed up), as well as responses to external food cues (e.g. finding it difficult saying no to food). The questions are provided with 4 - point Likert type scales. The response categories are: *never*, *sometimes*, *often*, *very often* or *not at all*, *a little*, *a lot*, *very much*. In the English version, response categories are numbered 0-3, with 0 representing no dysfunction. For practical reasons, i.e. comparison with the RAND 36-Item Health Survey 1.0 (RAND-36), item scores were recoded so that *higher scores* corresponded with *no dysfunction*. Each subscale score was transformed to give a common score range of 0-100, where 100 represents no dysfunction. Questions are answered without reference to a specific time frame. The questionnaire was adapted for use with Dutch speaking patients using both forward and backward translations.

In addition to the DHP, patients also completed the RAND-36, which is a reliable and valid generic measure of health status.<sup>12-16</sup> The RAND-36 contains eight dimensions of health: physical functioning, social functioning, role limitations (physical problem), role limitations (emotional problem), mental health, vitality, pain, and general health perception. In the official version one item was added measuring health change. For each dimension, item scores are coded, summed, and transformed on to a scale from 0 (worst health) to 100 (best health).<sup>15,16</sup>

All patients received a booklet comprising the Dutch version of the DHP and the RAND-36, which they were asked to complete at home. Respondents were asked to return the booklet to the outpatient department on their next visit, where it was checked for completeness by a trained diabetes specialist nurse.

#### *Medical examination*

Patients were examined according to a standardized protocol by a trained physician. For medical history a standardized questionnaire was used, containing questions about diabetes and its complications, co-morbidity, alcohol consumption, smoking, diabetes treatment, and educational level. Age was coded into six categories (31-40 years, 41-50 years, 51-60 years, 61-70 years, 71-80 years, and 81-90 years). The lowest educational level was defined as having attended primary school only. Hyperglycaemic complaints were considered to be present when patients had at least two of the following complaints: fatigue, weight loss, itching, thirst, increased amount of fluid intake or urine production. Diabetes complications were defined as having or having had macrovascular disease (coronary heart disease, cerebrovascular disease, or peripheral vascular disease), retinopathy, nephropathy, autonomic neuropathy, all defined according to international standards.<sup>11</sup> Co-morbidity consisted of the following diseases: chronic bronchitis, other lung diseases, serious back problems, rheumatism or articular complaints, cancer, diseases of the nervous system, and diseases of the thyroid gland. Body mass index (BMI) was calculated from weight and height ( $\text{kg/m}^2$ ).

#### *Analytical procedures*

The psychometric properties of the DHP were examined by item score distributions, inter-item correlations and scale intercorrelations, factor analysis, and Cronbach's  $\alpha$ .<sup>17</sup> The factor structure of the DHP was examined using a forced 3-factor Principal Axis Factoring (PAF) analysis. Convergent validity was investigated by examining the association between subscales scores of the DHP and related constructs of the RAND-36: We hypothesized strong positive correlations ( $> .40$ ) between the dimensions

Psychological distress/Barriers to activity of the DHP and the mental state, social functioning, vitality, and General Health Perception dimensions of the RAND-36. We did not expect strong correlations between the Disinhibited eating dimension and any of the RAND-36 dimensions. To investigate discriminant validity of the DHP, we examined whether the DHP discriminated between groups of individuals by age and sex. According to earlier results of the DHP, it was hypothesised that women would have lower scores (more problems) and older patients would have higher scores (less problems) on the Disinhibited eating dimension. Stepwise multiple regression analysis was used to examine the relationship between diabetic/comorbidity factors and health-related quality of life outcomes as measured by the DHP. A p-value of 0.05 or lower was considered to be statistically significant. Test-retest reliability was not examined in this study. Due to missing values, the number of respondents included in the analysis differs per analysis.

## RESULTS

General characteristics. Ninety-nine subjects referred by 71 general practitioners were included in the study (table 1). Forty-eight men and 51 women were included, all but one living independently. For women educational level was low, with two-thirds having finished primary school only. Forty-seven (47%) of the 99 patients had two or more complaints that were attributable to hyperglycaemia. Of all patients screened: 21 patients (21.2%) had no diabetes complications at all; 32 (32.3%) had one; 32 (32.3%) two; 11 (11.1%) three and 3 (3.0%) all four. Sixty-one percent of the women were diagnosed with hypertension, compared to 38% of the men ( $p < 0.03$ ). The percentage of men (71%) who drank alcohol was significantly higher, as compared to women (24%),  $p < 0.001$ . There was a highly significant difference in BMI between men and women ( $25.6 \pm 3.3$  vs  $29.3 \pm 5.2$  kg/m<sup>2</sup>,  $p < 0.001$ ).



**TABLE 1***General characteristics of 99 referred NIDDM patients*

Number of patients	99	
Male	48.5 %	
Age at referral (yrs)	61.2 ± 10.9	(range 31.3-83.6)
Age at onset DM (yrs)	52.8 ± 10.6	(range 15.0-78.0)
Known duration DM (yrs)	8.5 ± 7.3	(range 0.1-45.2)
Duration OHA-use (yrs)	6.7 ± 5.3	(range -0.4 <sup>#</sup> - 21.9)
Hypergl. complaints (≥ 2)	47.5 %	
GHb <sup>1</sup>	10.4 ± 2.7 %	(range 5.2-17.8)
Total cholesterol (mmol/l) <sup>2</sup>	6.4 ± 1.5	(range 3.0-14.0)
BMI (kg/m <sup>2</sup> )	27.5 ± 4.8*	(range 18.0-50.0)
Macrovascular complications	42.4 %	
CHD	12.1* %	
CVA/TIA	6.1 %	
PVD	34.3 %	
Microvascular complications	69.7 %	
Autonomic neuropathy	32.3 %	
Nephropathy	51.5 %	
Retinopathy	16.3 %	
Hypertension	49.5* %	
Co-morbidity	35.4 %	

Data as mean ± SD or as number of patients (%);

# start OHA-therapy after inclusion in this study

\* statistical significance between men and women,  $p < 0.01$ <sup>1</sup> GHb ≤ 8.0 % (good metabolic control)<sup>2</sup> Serum total cholesterol < 6.5 mmol/l (normal value)

### *Factor structure*

The results of the 3 forced Principal Axis factoring of the 31 items of the DHP accounted for 32% of the total explained variance (table 2). In this analysis we found similar but not identical factors to the original version of the DHP with 23 of the 31 items loading on the same factors identified in earlier findings (table 3).<sup>10</sup> Eight items (2, 3, 4, 6, 9, 11, 12, and 19) loaded on different factors as shown in table 2 and 3. Seven of these items came from the 'Psychological distress' dimension. Three items, item 15 ('wished never born'), item 3 ('hurt oneself'), and item 19 ('looks forward to the future') loaded below 0.30. The original factor structure and the outcome of our factor analysis correlated strongly with each other: 'Psychological distress' with 'Factor 2' ( $r=0.83$ ), 'Barriers to activity' with 'Factor 1' ( $r=0.94$ ), and 'Disinhibited eating' with 'Factor 3' ( $r=0.91$ ). Six items (item 4, 6, 12, 13, 22, and 29) loaded  $> 0.30$  on two factors. Four of these items (item 12, 13, 22, and 29) loaded on 'Barriers to activity' *and* 'Psychological distress' and two of them (item 4 and 6) loaded on the 'Barriers to activity' *and* 'Disinhibited eating' dimensions.

**TABLE 2**  
*Initial forced 3-factor Principal Axis Factoring (PAF) analysis. Varimax rotated factor structure*

ITEM*	FACTOR 1 (± BAR) <sup>1</sup>	FACTOR 2 (± PSY) <sup>2</sup>	FACTOR 3 (± EAT) <sup>3</sup>
<i>Factor 1</i>			
18 Worry about going into diabetic coma	66		
32 Difficult staying out late	65		
20 Nagging fear of hypos	64		
12 Touchy/moody about diabetes	51	40	
30 Difficult doing things	50		
17 Edgy when out and nowhere to eat	49		
21 Worry about colds or flu	47		
22 Frightened in busy/crowded shops	47	41	
8 Avoid going too far in case of hypos	42		
29 Days tied to meal times	40	33	
11 Tension headaches	40		
9 Because of diabetes cries/feels like crying	34		
1 Avoid going out if sugars on low side	32		
5 Worry about doing too much and going hypo			
<i>Factor 2</i>			
16 Lose temper/shout due to diabetes		77	
10 Lose temper over small things		67	
7 Lose temper over testing/diet		54	
26 More arguments at home		53	
2 Throw things when upset/lose temper		50	
13 Because of diabetes get depressed	33	50	
14 Wished dead		48	
15 Wished never born			
<i>Factor 3</i>			
24 Eat something extra when bored			63
28 Hard saying no to food			59
27 Eat to cheer self up			59
23 Wished not so many nice things to eat			55
25 Not easy to stop eating			50
6 Food controls life	47		49
4 Wish diabetes would just go away	30		32
3 Hurt self when upset			
19 Looks forward to the future			
% Variance	18.7	7.7	5.1

\* Items in abbreviated form. Factor loading < 0.30 omitted. Decimal points omitted for clarity.

<sup>1</sup> Barriers to activity (Bar) ≈ Factor 1

<sup>2</sup> Psychological distress (Psy) ≈ Factor 2

<sup>3</sup> Disinhibited eating (Eat) ≈ Factor 3

**TABLE 3***Item mean scores for the total sample*

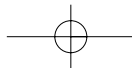
	ITEM <sup>1</sup>	MEAN <sup>2</sup>	FACTOR MEADOWS <sup>3</sup>	FACTOR ZS <sup>4</sup>
12	1 Avoid going out if sugars on low side	86.4 ± 25.3	Bar	Factor 1
	2 Throw things when upset/lose temper	94.2 ± 12.7	Psy	Factor 1
	3 Hurt self when upset	96.6 ± 15.5	Psy	Factor 3
	4 Wish diabetes would just go away	97.3 ± 9.2	Psy	Factor 3
	5 Worry about doing too much, going hypo	91.2 ± 17.0	Bar	Factor 1
	6 Food controls life	72.5 ± 29.1	Bar	Factor 3
	7 Lose temper over testing/diet	75.2 ± 28.8	Psy	Factor 2
	8 Avoid going too far in case of hypos	93.5 ± 18.3	Bar	Factor 1
	9 Because of diabetes cries/feels like crying	94.6 ± 15.7	Psy	Factor 1
	10 Lose temper over small things	71.8 ± 23.6	Psy	Factor 2
	11 Tension headaches	81.3 ± 26.3	Psy	Factor 1
	12 Touchy/moody about diabetes	84.0 ± 20.4	Psy	Factor 1
	13 Because of diabetes get depressed	85.7 ± 21.9	Psy	Factor 2
	14 Wished dead	94.6 ± 12.4	Psy	Factor 2
	15 Wished never born	96.9 ± 12.7	Psy	Factor 2
	16 Lose temper/shout due to diabetes	88.1 ± 21.0	Psy	Factor 2
	17 Edgy when out and nowhere to eat	85.0 ± 22.5	Bar	Factor 1
	18 Worry about going into diabetic coma	89.1 ± 22.8	Bar	Factor 1
	19 Looks forward to the future	45.2 ± 31.5	Psy	Factor 3
	20 Nagging fear of hypos	93.9 ± 16.8	Bar	Factor 1
	21 Worry about colds or flu	82.7 ± 26.8	Bar	Factor 1
	22 Frightened in busy/crowded shops	83.3 ± 26.3	Bar	Factor 1
	23 Wished not so many nice things to eat	74.8 ± 29.5	Eat	Factor 3
	24 Eat something extra when bored	57.5 ± 24.8	Eat	Factor 3
	25 Not easy to stop eating	67.4 ± 29.1	Eat	Factor 3
	26 More arguments at home	93.5 ± 17.0	Psy	Factor 2
	27 Eat to cheer self up	87.1 ± 19.5	Eat	Factor 3
	28 Hard saying no to food	67.7 ± 27.7	Eat	Factor 3
	29 Days tied to meal times	71.4 ± 30.7	Bar	Factor 1
	30 Difficult doing things	84.9 ± 24.5	Bar	Factor 1
	31 Plan day around injections	Question omitted		
	32 Difficult staying out late	92.5 ± 17.6	Bar	Factor 1

<sup>1</sup> Items in abbreviated form

<sup>2</sup> The means and standard deviations are derived from raw scores following transformation of minimum 0 to maximum 100 (increased scores represent increased functioning)

<sup>3</sup> Factor analysis Meadows10 (Psychological distress = Psy, Barriers to activity = Bar, Disinhibited eating = Eat)

<sup>4</sup> Factor analysis Zwolle Study (ZS)



#### *Item score*

Three of the 31 items (item 3, 4, and 15) had a mean score higher than 95.0 (table 3). The mean scores for all dimensions of the DHP and the RAND-36 were high (table 4). Inspection of the probability plots showed no abnormally skewed distribution of the DHP dimensions. The average inter-item correlation for the 'Psychological distress' dimension was 0.16 (range: -0.10 - 0.62). Item 19 ('looks forward to the future') did not correlate with the other items. On removal of this item, the average inter-item correlation increased from 0.04 to 0.20. The average inter-item correlation for the 'Barriers to activity' dimension was 0.25 (range: -0.02 - 0.60), for the 'Disinhibited eating' dimension 0.36 (range 0.26 - 0.46).

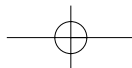
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**TABLE 4**

*DHP and RAND-36. Subscale score distribution characteristics*

SUBSCALE	ITEMS	MEAN	MEDIAN	RANGE	$\alpha$
Psychological distress	14	85.6 $\pm$ 9.4	88.1	54.8-100	0.72
Barriers to activity	12	85.5 $\pm$ 13.0	88.9	30.6-100	0.79
Disinhibited eating	5	70.9 $\pm$ 18.2	73.3	26.7-100	0.72
Physical functioning	10	71.5 $\pm$ 25.6	80.0	0.0-100	0.91
Social functioning	2	82.0 $\pm$ 24.4	100.0	0.0-100	0.81
Funct. role impairment	4	67.4 $\pm$ 42.4	100.0	0.0-100	0.92
Emot. role impairment	3	72.8 $\pm$ 41.0	100.0	0.0-100	0.91
Mental state	5	76.2 $\pm$ 18.3	80.0	20.0-100	0.85
Pain	2	75.8 $\pm$ 27.3	89.8	10.2-100	0.80
Vitality	4	57.7 $\pm$ 27.4	62.5	0.0-100	0.90
General health perception	5	62.6 $\pm$ 23.0	65.0	0.0-100	0.93
Health change	1	42.1 $\pm$ 21.1	50.0	0.0-100	-

The means and standard deviations are derived from raw scores following transformation of minimum 0 to maximum 100 (increased scores represent increased functioning)



## CHAPTER 1

*Reliability and validity*

In the following analyses we used the item-groupings of the DHP as reported by Meadows et al.<sup>10</sup> The internal consistency (Cronbach's  $\alpha$ ) of the scales of the DHP was found to be satisfactory for the DHP dimensions (table 4). Again item 19 ('looks forward to the future') had the lowest correlation with the scale. When omitted, Cronbach's  $\alpha$  of the 'Psychological distress' dimension increased from 0.72 to 0.77.

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As shown in table 5, the 'Psychological distress' and 'Barriers to activity' dimensions were strongly correlated with each other and with the predicted RAND-36 dimensions. The 'Disinhibited eating' dimension has a significant correlation with the 'mental state' and 'vitality' dimension of the RAND-36.

**TABLE 5**

*Correlations (Spearman) between DHP scales and scales of the RAND-36*

		PSYCHO- LOGICAL DISTRESS	BARRIERS TO ACTIVITY	DIS- INHIBITED EATING
<i>DHP</i>				
1	Psychological distress	1.00		
2	Barriers to activity	.48*	1.00	
3	Disinhibited eating	.27*	.21*	1.00
<i>RAND-36</i>				
7	Physical functioning	.28*	.41**	.07
8	Social functioning	.42**	.65**	.21
9	Role limitations (physical problem)	.30**	.49**	.16
10	Role limitations (emotional problem)	.30**	.42**	.24
11	Mental state	.56**	.57**	.30**
12	Pain	.31**	.50**	.18
13	Vitality	.44**	.59**	.37**
12	General health perception	.33**	.42**	.21
13	Health change	.36**	.41**	.22

\* p < 0.01

\*\* p < 0.001

## INTRODUCTION

*DHP outcome and patient characteristics*

Stepwise multiple regression of the patient characteristics described in table 1 and the DHP dimensions showed that only the hyperglycaemic complaint 'fatigue' had a significant predictive value on the 'Psychological distress' and 'Barriers to activity' dimensions. Patients reporting fatigue had a lower score (more problems) on the above-mentioned dimensions, ( $r^2 = 0.10$  and  $0.17$ ). The outcome of the 'Disinhibited eating' dimension was significantly influenced by age (younger, more problems), hypertension (if present, more problems), and retinopathy (if present, more problems,  $r^2 = 0.23$ ). There were no associations found between DHP scores and other patient characteristics (including chronic diabetes complications) as described in table 1. Chronic diabetes complications and co-morbidity correlated, although modestly, with the RAND-36 dimensions 'physical functioning' and 'pain' ( $p < 0.05$ ).

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## DISCUSSION

In this study we examined the psychometric properties of a new disease specific questionnaire, the Diabetes Health Profile (DHP) in a group of NIDDM patients referred for insulin therapy. The DHP was originally developed for insulin-dependent or insulin-requiring patients.

We found a high level of similarity between our factors and the original structure of the DHP, despite the difference in patient groups. The three factors accounted for no more than 32% of the total variance, leaving over half of the variance unexplained. This result, however, does compare with the studies of Meadows et al., in which the three factors accounted for 35% of the total variance.<sup>10</sup> The loading of some items on different factors could be explained by the fact that 'Psychological distress' and 'Barriers to activity' may measure to some extent the same trait in this sample of patients, which is also shown in their interscale correlation coefficient ( $r = 0.48$ ). Item 19 ('looks forward to the future') loads very low (0.16) and this item does not load on the expected 'Psychological distress' factor. Its mean score is very low and the score distribution is normal, whereas responses to other items are mostly positively skewed, which could lead to a low correlation between item 19 and the other items and thus to a low factor loading. Also, one must take into account that factor analysis in a small group of patients ( $n = 99$ , Meadows et al.<sup>10</sup> used a group of  $n = 2239$  patients), may result in a less stable factor solution. However, the high correlations between our factor structure and the original structure, together with a satisfactory Cronbach's  $\alpha$ , provides supportive evidence for the construct validity of the Dutch version of the DHP, despite the small sample size.

## CHAPTER 1

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In our study, the item scores differ from those reported in the insulin-dependent/requiring diabetes patients of Meadows et al.<sup>10</sup>, with a third of the items having a higher score in our patient group, indicating that most people reported less problems. The difference in these results could be explained by the difference in age and type of diabetes and their respective therapies. A further possibility is that older people, as in our research (mean age  $61.2 \pm 10.0$  years) may not recognize and could be less willing to respond to items such as 'throwing things', 'feel like crying', 'lose temper', 'more arguments at home'. Meadows et al.<sup>10</sup> reported a lower score (59.7 vs. 97.3) on item 4 ('wish diabetes would just go away'), which may be explained by the fact that younger people may have more difficulty in accepting a chronic disease. The item ('looking forward to the future') also differs considerably (our study: 45.2 vs. 74.5). An explanation may be that for older people future expectations may be of less relevance and that they are aware that their physical health may diminish in the future. One could suggest omitting item 19 ('looks forward to the future') because it lowers the internal consistency (Chronbach's  $\alpha$ ) as well as failing to contribute to the factor analysis. However, it does provide additional information about patients' thoughts concerning the future, and it would be interesting to examine changes in response when patients will be strictly regulated. The majority of our NIDDM patients were having hyperglycaemic complaints and did not experience any hypoglycaemia, which could explain the high score on the 'fear for hypo' questions. This may indicate that these items can be removed following further evaluations.

As predicted, the 'Psychological distress' and 'Barriers to activity' subscales correlated highly with 'mental state', 'social functioning', and 'vitality' of the RAND-36, which is comparable with the results found by Meadows et al.<sup>10</sup>, thereby providing initial evidence in support of the convergent validity of the DHP in this group of patients. However, the remaining dimensions of the RAND-36 also correlated with the 'Psychological distress' and 'Barriers to activity' dimension, although less stronger. In contrast, the 'Disinhibited eating' dimension is measuring something different in comparison with the RAND-36.

Older patients expressed less problems on the 'Disinhibited eating' dimension, which was also found in the studies of Meadows et al.<sup>10</sup>, thereby providing initial evidence in support of the discriminant validity of the 'Disinhibited eating' dimension. It could be due to the small sample that we were unable to establish differences in the 'Psychological distress' and 'Barriers to activity' dimensions in terms of age. Compared to older patients, younger patients may be more preoccupied with food, appearance, and restrictions in diet. There was no difference found in the 'Disinhibited eating' outcome between men and women in our (older) study group, which supports the finding of Meadows et al.<sup>10</sup>, who



## INTRODUCTION

found differences only in younger patients. One of the main features of hyperglycaemia, 'fatigue', was significantly associated with reported 'Psychological distress' and 'Barriers to activity' scores. It is possible that these patients are more susceptible to the dimensions which measure mood, irritability and anxiety. Most patients with hypertension reported more problems in the 'Disinhibited eating' dimension, which may be explained by the fact that most patients with hypertension also have a sodium-restricted diet, which is used to lower blood pressure.

The inability of the DHP to be sensitive to diabetic complications was surprising. This could be partly due to the fact that we measured the number of complications and not their severity. Also, chronic complications like nephropathy and autonomic neuropathy were asymptomatic prior to our medical examination. It is possible that in longitudinal studies, the DHP is more sensitive to changes in chronic diabetes complications. Jacobson et al. examined the psychometric properties and discriminant validity of the DQOL (Diabetes Quality of Life measure) and the Short Form (SF-36 = RAND-36) in IDDM (n = 111) and NIDDM (n = 129) patients in terms of diabetes related complications.<sup>18</sup> The DQOL was developed for evaluating Quality of Life in young IDDM patients (Diabetes Control and Complications Trial).<sup>19</sup> Three of the four dimensions of the DQOL were found to be sensitive to the severity of complications in IDDM patients. In the same study, the SF-36 was found to be sensitive to the severity of complications of both IDDM and NIDDM patients. In our study, we found a relationship between the number of diabetes complications and scores of the RAND-36: physical functioning and pain dimensions ( $p < 0.05$ ). These findings may suggest that the DHP and the RAND-36 can supplement each other and provide additional information regarding clinically relevant issues. As already suggested, it may be useful to assess quality of life with multiple instruments that measure generic and illness-specific issues.<sup>18-20</sup>

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## CONCLUSION

Overall, despite the small and different patient groups, the psychometric properties of the Dutch version of the DHP were similar to those reported by Meadows et al.<sup>10</sup> suggesting that it may also be satisfactory for use with NIDDM patients. Clearly, evaluation of the DHP in a larger sample of NIDDM patients is required to further examine its usefulness in this group of patients.

## CHAPTER 1

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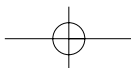
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## CHAPTER 2

## APPENDIX

## DIABETES HEALTH PROFILE (DHP)

- 20
- 1 Do you avoid going out if your sugars are on the low side?
  - 2 Do you throw things around if you get upset or lose your temper?
  - 3 Do you hurt yourself or feel like hurting yourself when you get upset?
  - 4 Do you wish your diabetes would just go away when things get on top of you?
  - 5 Do you worry about doing too much and going hypo?
  - 6 Does food control your life?
  - 7 Do you lose your temper if people keep on at you about sugar testing or diet?
  - 8 Do you avoid going out too far on your own in case of hypos?
  - 9 Because of your diabetes do you cry or feel like crying?
  - 10 Do you find yourself losing your temper over small things?
  - 11 Do you get tension headaches?
  - 12 Do you get touchy or moody about diabetes?
  - 13 Because of your diabetes do you get depressed?
  - 14 Do you even for a moment wish you were dead?
  - 15 Do you wish that you had never been born?
  - 16 Does your diabetes cause you to lose your temper or shout?
  - 17 Do you get edgy when you are out and there is nowhere to eat?
  - 18 Do you worry about going into a diabetic coma?
  - 19 Do you look forward to the future?
  - 20 Do you have a nagging fear of hypos?
  - 21 Because of your diabetes do you worry about getting colds or flu?
  - 22 Do you find it frightening or worrying going into busy or crowded shops?
  - 23 Do you wish there were not so many nice things to eat?
  - 24 How likely are you to eat something extra when you feel bored or fed up?
  - 25 When you start eating how easy do you find it to stop?
  - 26 Are there more arguments or upsets at home then there would be if you didn't have diabetes?
  - 27 Do you have problems keeping to your diet because *you eat to cheer yourself up?*
  - 28 Do you have problems keeping to your diet because *you find it hard saying no to food you like?*
  - 29 Does having diabetes mean *your days are tied to meal times?*
  - 30 Does having diabetes mean *it's difficult doing things when you want to?*
  - 31 Does having diabetes mean *you have to plan your day around injections?*
  - 32 Does having diabetes mean *it's difficult staying out late?*



IMPORTANCE OF GLYCEMIC CONTROL IN NIDDM

